

### **REMARKS**

Claims 1-9, 11-15, 17, 18, 20-48, 50, 52-66, 78-92, and 94-104 are now pending in the application. Claims 67-77 and 91-93 are canceled by this amendment and Claims 94-104 are added by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **APPLICANTS' INTERVIEW SUMMARY**

Applicants thank the Examiner for the interview granted with Applicants' representative on April 9, 2010. During the interview, various amendments to the independent claims were discussed with the Examiner. No agreement as to allowability of the claims was reached with the Examiner during the interview. However, Applicants believe that an agreement was reached that various features, such as displaying a progression of a procedure and determining a position of an external soft tissue are at least not found in the art cited in the current rejections.

Further, Applicants believe that an agreement was reached that the Examiner would contact Applicants representative prior to mailing any further office actions if all of the claims are not found to be in condition for allowance, to discuss possible further Examiner's amendments to place the claims in condition for allowance.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 1-9, 11-15, 17-18, 22-30, 33-44, 47-48, 50, 52-73, 77-80, 82, 85, 88 and 92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al.

(U.S. Pat. No. 6,226,548; hereinafter "Foley") in view of Ellis (U.S. Pat. Pub. No. 2003/0011624; hereinafter "Ellis"). Claims 20-21, 31-32, 45-46 and 75-76 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, as applied to claims 1, 22, 33 and 67, and further in view of Acker et al. (U.S. Pat. No. 6,332,089; hereinafter "Acker"). Claims 81, 84, 87, 90 and 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, as applied to claims 1, 22, 33, 53 and 67, and further in view of Rasche et al. (U.S. Pat. Pub. No. 2001/0034480) ("Rasche"). Claims 82-83, 85-86, 88-89 and 92-93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, and further in view of Shluzas (U.S. Pat. No. 6,648,888) ("Shluzas"). These rejections are respectfully traversed.

Previously Applicants have discussed the various references used to reject the claims, and do not repeat the same here but incorporates by reference Applicants previous arguments.

### **Claim 1**

Independent Claim 1 has been amended as supported by the application as filed at least in paragraph 68 and Figs. 4A-4C and 12B, to identify a first pedicle screw member, a second elongated rod member, and a third pedicle screw member. Accordingly, the first pedicle screw member and the third pedicle screw member are positionable relative to one another and the second elongated rod member is positionable relative to the first pedicle screw member and the third pedicle screw member. Independent Claim 1 has further been amended to recite "a first localization

element selectively and removably fixed to said first pedicle screw member having a depressable screw member to operate an internal mechanism to engage and disengage from said first pedicle screw member.” Applicants respectfully submit that neither Foley nor Ellis disclose such a mechanism to engage and disengage any element that could reasonably be interpreted as a localization element from a pedicle screw member. Foley, in particular, discloses a head positioning probe 280 (See Figs. 7 and 8). Foley discloses that the probe 280 can be used to move a multi-axial screw by performing a manipulation to a final position. See, Foley, col. 10, Ins. 45-51. Foley then states “Then, . . .an optically tracked rod inserter 245 . . . can be placed through another small incision to mate with and guide a rod 360 through the holes or slots of the screw heads 245.” Accordingly, Foley appears to teach a sequential process where the probe 280 orients the screws by tracking the probe 280 and then only tracking the rod to position the rod through the screws with the inserter 245. Ellis is directed to acquiring atlas data and morphing it to dimensions of a patient in a patient coordinate system. See, Ellis, Abstract. Accordingly, Ellis does not overcome any of the failings of Foley to render obvious at least the first localization element as recited in Independent Claim 1.

Additionally, Independent Claim 1 has been further amended to recite “a processor configured to: . . . assist in navigation of said third pedicle screw member relative to at least one of said first pedicle screw member or said second elongated rod member including generating icons for display on a display device without patient image data displayed on the display device.” As previously submitted, Applicants respectfully submit that Foley is directed to an image based system to illustrate the position of the screw heads and a rod relative to image data of the patient. Accordingly, maintaining

attachment of a localization element to a pedicle screw is unnecessary in the system of Foley as the screw is illustrated relative to the anatomy during movement of the rod. See, Foley, col. 10 and 11.

Independent Claim 1 further recites "track said first localization element while selectively fixed to said first pedicle screw member while tracking said second localization element while selectively fixed to said second elongated rod member." As previously argued and restated here, Ellis should not be combined with Foley to teach an imageless system, that being without patient image data displayed on a display device, as submitted by the Office. In particular, Ellis discloses that while various paradigms exist or are used, each has limitations. In particular, Ellis discloses "the imageless paradigm does not provide any image information, which compromises the ability of a physician to ensure that the relevant anatomical landmarks have been identified." See, Ellis, para. 16. Initially, Applicants note that this is directed to relating preoperative images to atlas data. See, Ellis, para. 15. Applicants respectfully submit that this is dissimilar from a surgical procedure including navigating a rod as disclosed by Foley and presently claimed. Moreover, any drawbacks or limitations of not providing image data are overcome by using image data of the patient as disclosed by Foley. Accordingly, Foley teaches away from an imageless system as disclosed in Ellis. Further, Independent Claim 1 specifically does not include image data and recites that the localization elements are tracked while selectively fixed to a pedicle screw and the elongated rod member. In other words, a tracked and known position of each of the elements being moved relative to one another is maintained with a tracking system and

processor, as recited in Independent Claim 1, accordingly, not requiring the known relative position of the screw relative to the anatomy as disclosed in Foley.

Accordingly, Independent Claim 1 is in condition for allowance in light of the cited art.

Moreover, Applicants respectfully submit that claims that depend directly or indirectly from Independent Claim 1 also include patentable subject matter. For example, dependent Claim 14 is directed to a navigable needle to determine the position of a third pedicle screw member relative to a first pedicle screw member and second elongated rod member. Applicants respectfully submit that the cited art does not anticipate or render obvious a navigable needle as recited in Independent Claim 14. Additionally, Claim 16 is directed to a processor providing alignment of the first pedicle screw member or the second elongated rod member in at least two plains. Dependent Claim 80 is directed to the first tracking element and the second tracking element having first and second shapes such that the processor can uniquely identify each of said first pedicle screw member and said second elongated rod member. As discussed above, allowing for continuous tracking of the first pedicle screw member and the second elongated rod member allows for overcoming any limitation of an imageless system by allowing for maintained determination of the location of the elements moving relative to one another. Accordingly, uniquely identifying the various portions not only provides information to the navigation processor, but is not disclosed in the cited art where any two or more elements are tracked and uniquely identified by the first and second tracking elements.

Accordingly, claims that depend from Independent Claim 1 also include patentable subject matter and should be in condition for allowance in light of the cited art.

#### **CLAIM 22**

Independent Claim 22 has been amended to recite “a display to display a first icon representing a first location of the first member and a second icon representing a second location of the second member.” Independent Claim 22 is further directed to the tracking element remaining connected to the first member during movement and the processor is configured to determine a position of the second member relative to the first member in at least two planes. As discussed above, Applicants respectfully submit that Foley and Ellis do not anticipate or render obvious, either alone or in combination, a display displaying first and second icons of two members, one being a first member to engage a boney structure and the second being a member moveable relative to the first member.

In addition, Independent Claim 22 is amended to recite “wherein the substantially patient imageless display includes no images acquired of the patient and illustrating said first icon and said second icon representing the first member and the second member in at least two planes.” Accordingly, Independent Claim 22 identifies that there are no patient images of the patient and that the icons can be displayed to illustrate alignment in at least two planes. Applicants respectfully submit that support for the amendments to Claim 22 can be found in the application as filed, including at least Fig. 10B and the description related thereto. As discussed above, Applicants respectfully

submit that the cited art does not anticipate or render obvious a system including a tracking element that remains connected to the first member during movement of the navigable instrument, a display to display a first icon and a second icon, and a display displaying substantially no patient images while showing alignment of the icons in first and second planes.

Additionally, Applicants respectfully submit that the claims that depend directly or indirectly from Independent Claim 22 also include patentable subject matter. For example, dependent Claim 27 is directed to an imaging device to acquire images of the patient after positioning the first member and "display the acquired image data relative to said first icon and said second icon representing the first member and the second member." Dependent Claim 29 has been amended to recite that the planes are substantially orthogonal and include a view aligned with a longitudinal axis of the first member and a view transverse to the longitudinal axis of the first member. Again, support for the amendment to dependent Claim 29 can be found at least in Fig. 10B and in the associated description. Further, Applicants respectfully submit that a system as recited in dependent Claim 29 is not anticipated or rendered obvious by the art cited in the rejections. The cited art is silent as to displaying the icons in the recited planes.

Accordingly, Applicants respectfully submit that Independent Claim 22, and the claims that depend directly or indirectly therefrom, are in condition for allowance.

### **Claim 33**

Independent Claim 33 has been amended as supported by the application at least in paragraphs 81, 89 and 90, and other areas. In particular, Independent Claim 33

is directed to a method of implanting a construct including “tracking a position of a second member with a second tracking element connected to the second member while positioning the second member relative to the first member; navigating the third member relative to the first member and the second member, while tracking the first tracking element connected with the first member and tracking the second tracking element connected to the second member, including: determining with a processor a real time optimal position of the third member in the selected space . . . displaying an icon to represent the position of at least two of the first member, the second member, or the third member without displaying images acquired of the patient on the display.” As previously argued, Applicants respectfully submit that the cited art does not anticipate or render obvious tracking multiple tracking elements, including at least navigating a third member while tracking a first and second tracking element connected to first and second members. Additionally, the method recited in Independent Claim 33 is directed to determining with a processor a real-time optimal position of the third member in the selected space. Such a real-time determination is not disclosed by the art cited in the rejections. Accordingly, Applicants respectfully submit that Independent Claim 33 and the claims that depend directly or indirectly therefrom include patentable subject matter.

Additionally, claims that depend directly or indirectly from Independent Claim 33 also include patentable subject matter. For example, dependent Claim 95, added by this amendment and supported by the application as filed at least in paragraphs 89 and 90 and Figs. 4A-4C, recites “wherein connecting a tracking element includes depressing a member to actuate an internal mechanism to fixedly connect the tracking element to the first pedicle screw.” Applicants respectfully submit that the art cited in the rejections



does not anticipate or render obvious such an internal mechanism. While Shluzas discloses a reduction device having a pivotal jaw 80. The pivotal jaw 80 includes a pivotal portion 84 and a main body portion 82. An actuator shaft 106 is assembled to actuate the pivotal member 80 to engage a screw as illustrated throughout and described in at least columns 5 and 8. As illustrated in Figs. 21 and 23 of Shluzas, the pivotal member is exterior to the device and engages an exterior of the screw. Accordingly, Applicants respectfully submit that Shluzas actually teaches away from new Claim 95.

Further, dependent Claim 43 recites "wherein determining a real time optimal position includes processing with a processor regarding at least two planes a determination of a real time optimal position along at least two planes for the third member." Applicants respectfully submit that the cited art does not anticipate or render obvious determining a real-time optimal position and therefore can not anticipate or render obvious determining in two planes a real-time optimal position as recited in dependent Claim 43. Dependent Claim 44 is directed to displaying the icons in the two planes that are orthogonal to the members positioned in the patient, as discussed above which is not anticipated or rendered obvious by the cited art. Finally, dependent Claims 45 and 46 are directed to determining a contour of soft tissue and to determining an insertion point through the soft tissue. As discussed above, the art cited in the rejections is directed to using image data to identify portions of the anatomy. Accordingly, determining a soft tissue contour and using the contour to determine an insertion point is not anticipated or rendered obvious by that art cited in the rejections. In fact, the art appears to teach away from such a soft tissue determination. While Ellis

discloses a possibility of not using patient image data, Ellis disclose that such a system has limitations and does not propose a cure that renders obvious the method as recited in Claims 45 and 46. Rather, Ellis simply demonstrates and discloses that understanding the location of anatomical landmarks can limit a procedure and discloses merging image data to atlases. Accordingly, determining a contour as recited in dependent Claim 45 is not anticipated or rendered obvious by Ellis. Furthermore, none of the other cited art overcomes the failing of Ellis in determining a contour of soft tissue.

Accordingly, Independent Claim 33 and the claims that depend directly or indirectly therefrom, are in condition for allowance.

#### **Claim 53**

Claim 53 is also a method of implanting a construct that is directed to selecting a final orientation of at least one of three members relative to the other of the at least three members. Independent Claim 53 further is directed to navigably positioning in at least one vertebrae of a patient at least one of said first member, said second member, or said third member relative to another of at least one of said first member, said second member, or said third member to achieve the selected final orientation with the assistance of icons; and displaying a current position icon relative to the two or more icons to illustrate a current position of at least one of said first member, said second member, or said third member relative to the final orientation position without images of the patient.” Applicants respectfully submit that the cited art does not anticipate or render obvious selecting a final orientation, selecting a characteristic of a member,

navigably positioning a member in a vertebrae, and displaying a current position icon as recited in Independent Claim 53. As discussed above, Foley is directed to obtaining images of a patient and navigating a rod relative to the patient with the use of the images. Accordingly, Foley is not directed to navigably positioning a member, as recited in Independent Claim 53 and displaying a current position icon to illustrate a current position without images of the patient. Applicants respectfully submit that the other cited art does not overcome the failing of Foley. In particular, as discussed above, Ellis is directed to using atlas images as a way to overcome failings or limitations of an imageless system. Accordingly, displaying a selected position icon relative to at least two or more icons to illustrate a selected position as recited in Independent Claim 53 is not anticipated or rendered obvious by the art cited in the rejections. Applicants respectfully submit that support for the amendments to Independent Claim 53 can be found in the application as filed including at least paragraphs 105 and 146 and Fig. 12B.

Additionally, claims that depend directly or indirectly from Independent Claim 53 also include patentable subject matter. For example, dependent Claim 58 recites "wherein selecting a characteristic . . . with at least an assistance of a processor by processing determined positions of the first member and the second member." The amendment to dependent Claim 58 is supported by the application as filed including at least paragraphs 89 and 90. Applicants respectfully submit that the processor in assisting and determining a characteristic of a member is not anticipated or rendered obvious by the art cited in the rejections. Furthermore, the processor processes the characteristic based upon determined positions of a first and second member. Accordingly, dependent Claim 58 includes patentable subject matter.

New Claim 96 is added by the amendment and is supported by the application as filed including at least paragraphs 105 and 106 and Fig. 12B. Dependent Claim 96 recites "the current position icon includes a progress bar illustrating the amount of progress of movement of the third member." The progress bar can illustrate the extent of the progress towards the selected final orientation. Applicants respectfully submit that the cited art does not anticipate or render obvious a progress bar as recited in dependent Claim 96, and therefore is in condition for allowance.

#### **Claim 67**

Claims 67-77 and 91-93 are canceled by this amendment. Accordingly, the rejections thereto are rendered moot and Applicants respectfully request that they be withdrawn.

#### **New Claims**

Claims 97-104 are added by this amendment and are supported by the application as filed including at least paragraphs 83-90, 95-105, 146 and Fig. 6. These new claims are directed to a method of implanting construct of at least a first pedicle screw, a second pedicle screw, and a third elongated rod. Independent Claim 97 is directed to removably and fixedly connecting a first tracking element to the first pedicle screw and a second tracking element to the second pedicle screw and "tracking a position of the second pedicle screw member in the selected space with the second tracking member with the second member; determining an alignment in a first plane and an alignment in the second plane of the first pedicle screw member and the second

pedicle screw member.” As discussed above, Applicants respectfully submit that removably and fixedly connecting a first tracking element and a second tracking element to respective first pedicle screw member and a second pedicle screw member is not anticipated or rendered obvious by the art cited in the rejections. Additionally, the method of Claim 97 is directed to determining alignment of a first plane and an alignment in the second plane of the first and second pedicle screws. Applicants respectfully submit that the art cited in the rejections does not anticipate or render obvious determining alignment in the first and second plane. As discussed above, and illustrated in Figs. 12-13 of Foley, Foley is directed to orienting screw heads for connection with the rod.

Independent Claim 97 further recites “determining a characteristic of a third elongated rod member to achieve a determined alignment in the first plane and second plane” and “determining a real-time position of the third elongated rod member relative to at least one of the first pedicle screw member or the second pedicle screw member with the respective connected first, second, and third tracking elements.” As discussed above, determining a characteristic and determining a real-time position of an elongated rod member is not anticipated or rendered obvious by the art cited in the rejection. This is further distinguished from the cited art in that Independent Claim 97 recites “displaying . . . without displaying representations of the boney structure.” As discussed above, Foley is directed to displaying images of a patient when performing a procedure. Ellis is directed to the use of atlas data to overcome the limitations of an imageless system. Accordingly, the determination of a characteristic, determining a real-time

position of the elongated rod member; and displaying an icon without representation of a boney structure is contrary to Foley and Ellis, either alone or in combination.


Additionally, claims that depend directly or indirectly from new Independent Claim 97 also include patentable subject matter. For example, dependent Claim 98 is directed to displaying an entry point icon, dependent Claim 99 is directed to using a probe to determining a soft tissue position as apart of the method of displaying an entry point icon, dependent Claim 100 is directed to displaying a progress icon, and dependent Claim 101 is directed to determining a characteristic of a processor system. Applicants respectfully submit that the cited art does not anticipate or render obvious these features as well and they are supported by the application as filed, as least in the areas discussed above relating to the other amendments in the current amendment. Accordingly, all of the new claims are supported by the application as filed and in condition for allowance.

## CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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